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UNIT DOSE CONTAINER

This invention relates to a thermoplastic container suitable for use in holding and transferring injectable solutions to a syringe.

There are many different forms of syringe which are presently available for use by the medical professions. The most appropriate syringe design for any one situation depends largely on the particular circumstances of use, the nature of the solution being injected and the location of the intended injection.

One particular design difference between various syringes is the manner in which the open end is shaped to accommodate a hypodermic needle. The two most popular forms of needle fitting are the friction fit fitting (such as the luer slip fitting) and the combination of screw thread and friction engagement fitting (such as the luer lock fitting). Screw thread engagement fittings of interest in the context of the present invention are female fittings having an internal thread such as in the case of the luer lock fitting and all references to screw thread engagement fittings on syringes hereafter are references to female fittings. A screw thread engagement fitting is the fitting of preference where the circumstances of use indicate that there is some prospect of the needle becoming disengaged with the syringe body (e.g. epidural injections). This invention is particularly concerned with containers suitable for transferring injectable solutions to syringes having a screw thread engagement fitting.

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Background Art

In the past, the general practice of surgeons or other medical practioners using hypodermic syringes has been to transfer an injection solution to a syringe from a glass vial using a broad channelled needle attached to the syringe body. Following transfer, this broad channelled needle has been removed from the syringe and replaced with a narrower channelled hypodermic needle suitable for injecting the solution into the patient. It will be appreciated that this past practice has necessitated the use of a number of separate components. Furthermore, as solution transfer for injecting into humans requires scrupulous sterilizing of components, this previous practice has required separate sterilizing measures to be taken at each step.

To avoid the problems of such transfer, it has been previously proposed to provide ampoules or vials holding a single dose. These single dose vials have been adapted to fit like cartridges into a syringe body onto which can be fitted a hypodermic needle. Such unit dose vials are normally manufactured from glass and sealed with a rubber membrane and the vial is punctured by attaching to the syringe body a double sided needle.

An alternative arrangement is disclosed in Australian patent 556,483 where a unit dose container is described made from a thermoplastic material which is adapted to be opened and co-operatively engaged directly onto a needle fitting on a syringe to which it is desired to transfer injection fluid. Whilst this patent describes a satisfactory arrangement for use with a standard friction fit needle

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fitting such as a luer slip fitting, it does not deal with the problems associated with syringes utilizing screw thread engagement systems such as the luer lock system.

It is an object of the present invention to provide a container suitable for use with a syringe having a screw thread engagement fitting to facilitate more secure, easier and more convenient transfer of an injection solution to a syringe which has a screw thread engagement fitting than has hitherto been possible.

Description of the Invention

According to the present invention, there is provided a liquid containing thermoplastic unit dose container which comprises a body portion, a neck portion and an outlet opening at the end of the neck portion which is sealed by a non resealable cap, wherein the outside wall of the neck portion comprises a thread engagement portion which is located at or proximate the outermost edge of the neck portion so that after removal of the cap the thread engagement portion is adapted to engage within an inwardly facing screw thread channel at the end of a syringe, thus enabling sealing connection of the container to the said syringe so that liquid within the container may be directly transferred from the container to the syringe.

The cap is preferably attached to the outlet opening along a weakened section so that it may be readily detached by a rocking or twisting action. Preferably, the outside wall of the container neck comprises a thread engagement portion and a non engagement portion. In such an embodiment, the thread engagement portion has a cross sectional diameter

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greater than the distance between the top of the thread on opposite sides of the syringe fitting and is adapted to engage in the screw thread channel of the syringe to facilitate connection.

The diameter of the non engagement portion is equal to or preferably smaller than the distance between the top of the thread on opposite sides of the syringe fitting so that it effectively clears the thread when the neck is drawn onto the screw thread of the syringe by the engagement of the thread engagement portion in the thread channel.

The thread engagement portion can be of any shape that will engage within the screw thread channel of the syringe fitting. Most preferably, the thread engagement portion of the neck is located at the edge of the outlet opening and comprises a shoulder shaped to fit within the screw thread channel of the syringe fitting. One example of a particular embodiment of the invention is a container having a cylindrical neck portion (being the non engagement portion) with a peripheral shoulder at the edge of the outlet opening forming the engagement portion. In other words, it is possible to form the container with parallel sides. If the screw thread fitting comprises a central cone such as in the luer lock fitting, it is preferred that these sides be sized to seal against the luer cone. Alternatively, the container may have an inverted truncated cone neck portion with the leading edge thereof being formed to engage with the thread on a syringe fitting (the thread engagement portion) and the trailing section of the truncated cone forming the non engagement portion of the neck.

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The container of the present invention is particularly useful for use with syringes having screw thread engagement fittings such as the "luer lock" fitting. The luer lock fitting comprises a central male cone, an outer peripheral wall and a bottom wall. The outside wall of the cone, the bottom wall and the inside of the peripheral wall together define an annular channel. On the inside of the peripheral wall there is provided a screw thread.

When used in conjunction with a syringe having a fitting like that of the luer lock, it is necessary that the outlet opening of the container be large enough to accommodate the central male cone on the syringe.

Thus according to one embodiment of the invention, the diameter of the neck portion is equal to or slightly smaller than the corresponding outside diameter of the cone on the syringe fitting at at least one portion of the container neck. As the container of the invention is of a thermoplastic material, it is capable of slight deformation and the diameter of the neck portion in at least one position is most preferably slightly smaller than the outside diameter of the syringe so to sealingly abut against the cone at that point or points.

Where sealing engagement is facilitated in this manner, it is not necessary that the engagement portion of the container neck also provide a seal with the fitting although this is desirable. It is however very important that sealing engagement occur either between the engagement portion of the neck and the peripheral wall of the fitting or alternatively between a portion of the inside of the container neck and the

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central male cone. If there is no sealing connection, it is possible for the intrusion of unsterile air into the container and this may lead to contamination of the container contents of the syringe.

Sealing between the container and the syringe fitting is also enhanced if the engagement portion of the neck is slightly greater in cross sectional diameter than the internal diameter of the annular channel. This means that upon engagement of the container with the syringe, the engagement portion slightly deforms and sealingly abuts against the inside of the peripheral wall.

The body of the container may be of any shape. However, it is preferred that the top of the body be formed hexagonally. The hexagonal form makes it easier to connect the syringe to the container as it strengthens the container in such a way that it can stand radial and axial strains better. The hexagonal upper part of the body is then further strengthened by one yoke on each side. The yokes also reduce the risk of the containers being punctured when they are being produced.

In use, the transfer of injection solution held within a container made in accordance with the invention is effected in the following way.

First, the non resealable container cap is removed by a rocking or twisting action and separates from the container along the weakened portion adjacent the outlet opening. The container is held in an upright position and the syringe into which it is intended to transfer the solution is placed so that the screw thread engagement fitting aligns with the

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outlet opening. The plunger in the syringe should be fully inserted. The container is then sealingly engaged with the syringe fitting by rotating the syringe and container with respect to each other until the container has completely engaged with the screw thread on the syringe. When so connected, the contents of the container may be conveniently withdrawn into the syringe by the rearward action of the plunger in the syringe body and if necessary, assistance in this fluid transfer may be given by partial deformation of the outside walls of the container.

The invention is further described below with reference to preferred embodiments of the invention shown in the accompanying drawings wherein:

Figure 1 illustrates a front view of a unit dose container made in accordance with the invention sealed by a non resealable cap;

Figure 2 illustrates the top part of the unit dose container of figure 1 with the cap removed from the outlet opening;

Figure 3 illustrates the top portion of an alternative embodiment of the invention.

Figure 4 illustrates the unit dose container of figure 2 with a syringe connected to the outlet opening thereof; and

Figure 5 is an exploded view of the connection between the outlet opening and the syringe fitting as illustrated in figure 4.

In figure 1 there is shown a container 1 of thermoplastic material which can be readily deformed. Suitable materials for the manufacture of such containers are

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well known in the art but include polyethylene and polypropylene. The container 1 comprises a body portion 2 and a neck portion 3. At the end of the neck portion, there is provided a non resealable cap 4 connected to the end of neck 3 along weakened line 5. Neck portion 3 is in the form of an outwardly widening truncated cone and this feature is easier to identify in figure 2.

In figure 3 there is shown an alternative embodiment of the invention wherein the top of the body is formed hexagonally and the body is strengthened by one yoke on each side.

The non resealable cap 4 may be removed from neck portion 3 by a rocking or twisting action and separates from the neck portion 3 along weakened line 5. After removal of the non resealable cap, there is revealed an outlet opening 7 at the end of neck portion 3 through which, liquid contained in container 1 may pass.

Neck portion 3 comprises a thread engagement portion being the shoulder 8 located about the peripheral edge of outlet 7. The neck portion also comprises a non engagement portion 9 of reduced cross sectional diameter. Figures 4 and 5 show the connection of such a container to a syringe so to facilitate transfer of the liquid contained in the container to the syringe. These figures illustrate a syringe having a luer lock needle fitting 10. This fitting has a central male cone 11, an outer peripheral wall 12 and a bottom wall 13. These walls form the boundary of an annular channel 14. A screw thread 15 is provided on the inside wall of peripheral wall 12. The central luer cone 11 is provided with a

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transfer channel 16 which is open at its outer most end 17.

In figure 3, the engagement portion has a less sharply defined edge. This shoulder is adapted to engage with the screw thread fitting of the syringe but may require continued application of force during connection with the screw thread to ensure engagement. The neck is strengthened by yokes 6 and the top of the package is hexagonally formed.

The container 1 is adapted to engage with the luer lock fitting 10 as follows. After the non resealable cap 4 is removed from container 1, it is held in an upright position and the syringe fitting 10 is located adjacent to the outlet opening 7 of container 1 whereby central luer cone 11 is inserted into the outlet opening 7. By relative rotation of the container with respect to the syringe fitting, thread engagement shoulder 8 on neck 3 is caused to engage with thread 15. To assist in initial engagement, the syringe fitting may be pushed slightly down into the outlet opening 7. Once the thread "takes", shoulder 8 fits behind the thread 15 and abuts against the underside 17 of the thread and the inside of peripheral wall 12. The non engagement portion 9 of neck 3 is of narrower cross section so that it does not interfere with the thread 15 but can move freely into channel 14 whilst the container is screwed onto the syringe fitting.

The internal diameter of neck 3 at point 19 is slightly smaller than the outside cross sectional diamter of cone 11. As can be seen in figure 5, this ensures sealing engagement between the components at the area generally designated by the numeral 20. The extent of the sealing at 20 improves as

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the container is screwed onto the luer lock fitting as in a standard luer cone, the side wall of the cone is slightly inclined with the base of the cone being of slightly increased diameter than the top of the cone.

Accordingly, as container 1 is screwed onto the screw thread fitting 10, that portion of the neck indicated at position 19 is forced outwardly to increase the internal diameter of the neck at this position. This causes stresses in the neck resulting in closer and tighter abuttment of portion 19 against the outside wall of cone 11 as the container is screwed onto the needle fitting.

In figure 5, there is also shown in hatch lines the position of the container once fully screwed onto the needle fitting. In this position, the top of the outlet opening 7 abuts against the base 13 of the needle fitting to further ensure sealing engagement of the container onto the needle fitting.

Once the container has been fully secured onto the needle fitting, transfer of the injectable solution in the container is easily effected by the rearward action of the plunger in the syringe body. Most preferably, the container side walls are flexible enough so that the container can partially collapse in the drawing out of the injection solution. Transfer of the solution can be assisted by squeezing the outside walls 21 of the container.

The container of the present invention can be filled with a solution of any drug which is suitable for injection but is particularly advantageous for use with aqueous solutions of autoclavable local anaesthetics such as

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lidocaine, prilocaine, mepivocaine, bupivocaine, etidocaine or other drugs which are used under conditions where the demands for easy handling and sterility are especially high.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into constructions and parts previously described without departing from the spirit or ambit of the invention as defined in the following claims.

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Claims:

1. A liquid containing thermoplastic unit dose container which comprises a body portion, a neck portion and an outlet opening at the end of the neck portion which is sealed by a non resealable cap, wherein the outside wall of the neck portion comprises a thread engagement portion which is located at or proximate the outermost edge of the neck portion so that after removal of the cap the thread engagement portion is adapted to engage within an inwardly facing screw thread channel at the end of a syringe, thus enabling sealing connection of the container to the said syringe so that liquid within the container may be directly transferred from the container to the syringe.

2. A container as claimed in claim 1 wherein the outside wall of the container neck comprises a thread engagement portion and a non engagement portion, said thread engagement portion being adapted to engage in the screw thread channel at the end of said syringe and said non engagement portion being shaped so that it does not interfere with the screw thread when the container is connected to the syringe.

3. A container as claimed in claim 2 wherein the thread engagement portion is located at the edge of the outlet opening and comprises a shoulder shaped to fit within the screw thread channel at the end of the syringe.

4. A container as claimed in any one of the previous claims wherein the neck portion is in the shape of an inverted truncated cone and the edge of the outlet opening is shaped to engage with the screw thread channel at the end of

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the syringe.

5. A container as claimed in any one of claims 1 to 3 wherein the neck portion has parallel sides.

6. A container according to any one of the previous claims wherein the top of the body is hexagonal and strengthened by one yoke on each side.

7. A container according to any one of the previous claims wherein the outlet opening is formed such that it is adapted to be screw threadingly engaged with a luer lock fitting.

8. A container as claimed in any one of the previous claims wherein the container is adapted to be connected to a syringe with a fitting comprising a central cone surrounded by a peripheral wall having an inwardly facing screw thread, characterized by the internal diameter of the neck portion of the container being less than or equal to the corresponding outside diameter of the central cone at at least one portion of the container neck.

9. A container as claimed in claim 8 wherein the engagement portion of the neck is greater in cross sectional diameter than the distance between opposite sides of the peripheral wall on the syringe to which it is intended to connect the container.

10. A container as claimed in any one of the previous claims wherein the non resealable cap is attached to the outlet opening along a weakened section.

11. A container substantially as hereinbefore described with reference to what is shown in any one of the accompanying drawings.

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ABSTRACT

A liquid containing thermoplastic unit dose container (1) which comprises a body portion (2), a neck portion (3) and an outlet opening (7) at the end of neck portion (3) which is sealed by a non re-sealable cap (4). The outside wall of the neck portion (3) comprises a thread engagement portion (8) which is located at or proximate the outermost edge of the neck portion (3) so that after removal of cap (4) thread engagement portion (8) is adapted to engage within an inwardly facing screw thread channel (14) at the end of a syringe. This enables sealing connection of the container (1) to the syringe so that liquid within container (1) may be directly transferred from the container (1) to the syringe.

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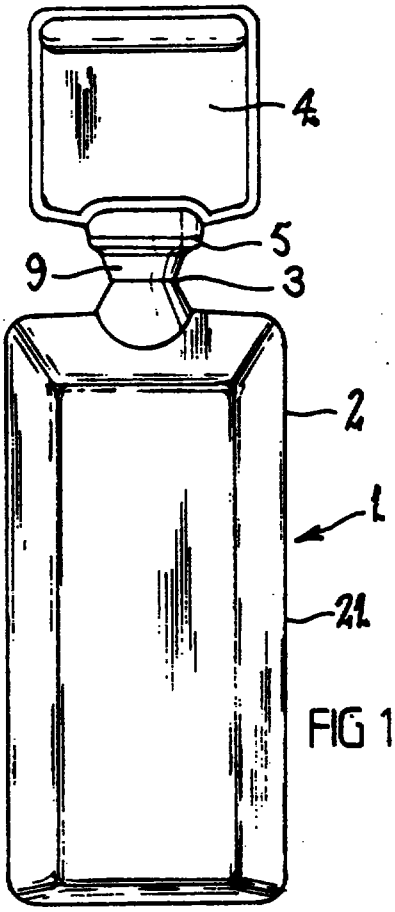


FIG 1

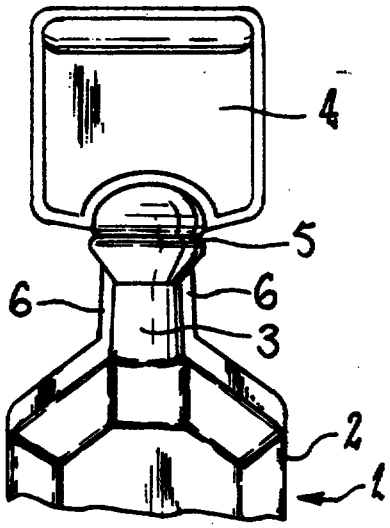


FIG 3

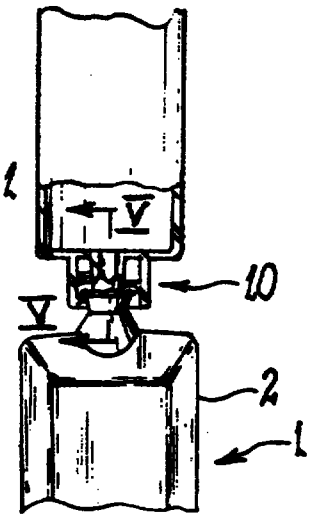


FIG 4

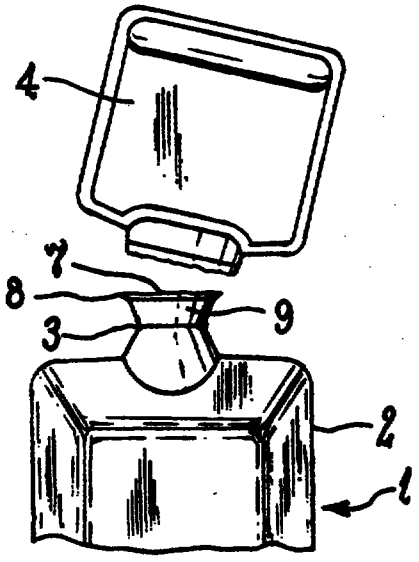


FIG 2

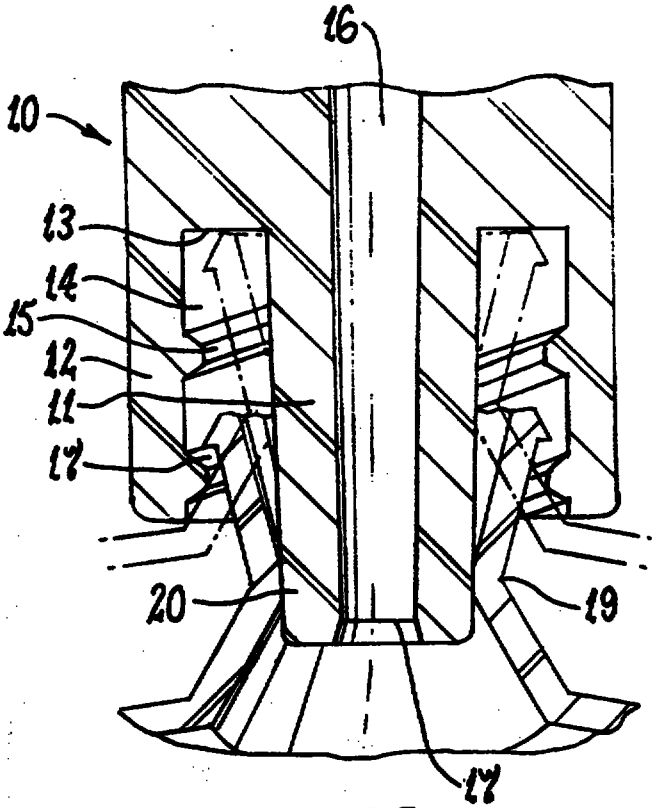


FIG 5

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UNIT DOSE CONTAINER

This invention relates to a thermoplastic container suitable for use in holding and transferring injectable solutions to a syringe.

There are many different forms of syringe which are presently available for use by the medical professions. The most appropriate syringe design for any one situation depends largely on the particular circumstances of use, the nature of the solution being injected and the location of the intended injection.

One particular design difference between various syringes is the manner in which the open end is shaped to accommodate a hypodermic needle. The two most popular forms of needle fitting are the friction fit fitting (such as the luer slip fitting) and the combination of screw thread and friction engagement fitting (such as the luer lock fitting). Screw thread engagement fittings of interest in the context of the present invention are female fittings having an internal thread such as in the case of the luer lock fitting and all references to screw thread engagement fittings on syringes hereafter are references to female fittings. A screw thread engagement fitting is the fitting of preference where the circumstances of use indicate that there is some prospect of the needle becoming disengaged with the syringe body (e.g. epidural injections). This invention is particularly concerned with containers suitable for transferring injectable solutions to syringes having a screw thread engagement fitting.

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Background Art

In the past, the general practice of surgeons or other medical practioners using hypodermic syringes has been to transfer an injection solution to a syringe from a glass vial using a broad channelled needle attached to the syringe body. Following transfer, this broad channelled needle has been removed from the syringe and replaced with a narrower channelled hypodermic needle suitable for injecting the solution into the patient. It will be appreciated that this past practice has necessitated the use of a number of separate components. Furthermore, as solution transfer for injecting into humans requires scrupulous sterilizing of components, this previous practice has required separate sterilizing measures to be taken at each step.

To avoid the problems of such transfer, it has been previously proposed to provide ampoules or vials holding a single dose. These single dose vials have been adapted to fit like cartridges into a syringe body onto which can be fitted a hypodermic needle. Such unit dose vials are normally manufactured from glass and sealed with a rubber membrane and the vial is punctured by attaching to the syringe body a double sided needle.

An alternative arrangement is disclosed in Australian patent 556,483 where a unit dose container is described made from a thermoplastic material which is adapted to be opened and co-operatively engaged directly onto a needle fitting on a syringe to which it is desired to transfer injection fluid. Whilst this patent describes a satisfactory arrangement for use with a standard friction fit needle

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fitting such as a luer slip fitting, it does not deal with the problems associated with syringes utilizing screw thread engagement systems such as the luer lock system.

It is an object of the present invention to provide a container suitable for use with a syringe having a screw thread engagement fitting to facilitate more secure, easier and more convenient transfer of an injection solution to a syringe which has a screw thread engagement fitting than has hitherto been possible.

Description of the Invention

According to the present invention, there is provided a liquid containing thermoplastic unit dose container which comprises a body portion, a neck portion and an outlet opening at the end of the neck portion which is sealed by a non resealable cap, wherein the outside wall of the neck portion comprises a thread engagement portion which is located at or proximate the outermost edge of the neck portion so that after removal of the cap the thread engagement portion is adapted to engage within an inwardly facing screw thread channel at the end of a syringe, thus enabling sealing connection of the container to the said syringe so that liquid within the container may be directly transferred from the container to the syringe.

The cap is preferably attached to the outlet opening along a weakened section so that it may be readily detached by a rocking or twisting action. Preferably, the outside wall of the container neck comprises a thread engagement portion and a non engagement portion. In such an embodiment, the thread engagement portion has a cross sectional diameter

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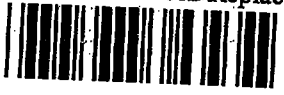
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greater than the distance between the top of the thread on opposite sides of the syringe fitting and is adapted to engage in the screw thread channel of the syringe to facilitate connection.

The diameter of the non engagement portion is equal to or preferably smaller than the distance between the top of the thread on opposite sides of the syringe fitting so that it effectively clears the thread when the neck is drawn onto the screw thread of the syringe by the engagement of the thread engagement portion in the thread channel.

The thread engagement portion can be of any shape that will engage within the screw thread channel of the syringe fitting. Most preferably, the thread engagement portion of the neck is located at the edge of the outlet opening and comprises a shoulder shaped to fit within the screw thread channel of the syringe fitting. One example of a particular embodiment of the invention is a container having a cylindrical neck portion (being the non engagement portion) with a peripheral shoulder at the edge of the outlet opening forming the engagement portion. In other words, it is possible to form the container with parallel sides. If the screw thread fitting comprises a central cone such as in the luer lock fitting, it is preferred that these sides be sized to seal against the luer cone. Alternatively, the container may have an inverted truncated cone neck portion with the leading edge thereof being formed to engage with the thread on a syringe fitting (the thread engagement portion) and the trailing section of the truncated cone forming the non engagement portion of the neck.

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The container of the present invention is particularly useful for use with syringes having screw thread engagement fittings such as the "luer lock" fitting. The luer lock fitting comprises a central male cone, an outer peripheral wall and a bottom wall. The outside wall of the cone, the bottom wall and the inside of the peripheral wall together define an annular channel. On the inside of the peripheral wall there is provided a screw thread.

When used in conjunction with a syringe having a fitting like that of the luer lock, it is necessary that the outlet opening of the container be large enough to accommodate the central male cone on the syringe.

Thus according to one embodiment of the invention, the diameter of the neck portion is equal to or slightly smaller than the corresponding outside diameter of the cone on the syringe fitting at at least one portion of the container neck. As the container of the invention is of a thermoplastic material, it is capable of slight deformation and the diameter of the neck portion in at least one position is most preferably slightly smaller than the outside diameter of the syringe so to sealingly abut against the cone at that point or points.

Where sealing engagement is facilitated in this manner, it is not necessary that the engagement portion of the container neck also provide a seal with the fitting although this is desirable. It is however very important that sealing engagement occur either between the engagement portion of the neck and the peripheral wall of the fitting or alternatively between a portion of the inside of the container neck and the

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central male cone. If there is no sealing connection, it is possible for the intrusion of unsterile air into the container and this may lead to contamination of the container contents of the syringe.

Sealing between the container and the syringe fitting is also enhanced if the engagement portion of the neck is slightly greater in cross sectional diameter than the internal diameter of the annular channel. This means that upon engagement of the container with the syringe, the engagement portion slightly deforms and sealingly abuts against the inside of the peripheral wall.

The body of the container may be of any shape. However, it is preferred that the top of the body be formed hexagonally. The hexagonal form makes it easier to connect the syringe to the container as it strengthens the container in such a way that it can stand radial and axial strains better. The hexagonal upper part of the body is then further strengthened by one yoke on each side. The yokes also reduce the risk of the containers being punctured when they are being produced.

In use, the transfer of injection solution held within a container made in accordance with the invention is effected in the following way.

First, the non resealable container cap is removed by a rocking or twisting action and separates from the container along the weakened portion adjacent the outlet opening. The container is held in an upright position and the syringe into which it is intended to transfer the solution is placed so that the screw thread engagement fitting aligns with the

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outlet opening. The plunger in the syringe should be fully inserted. The container is then sealingly engaged with the syringe fitting by rotating the syringe and container with respect to each other until the container has completely engaged with the screw thread on the syringe. When so connected, the contents of the container may be conveniently withdrawn into the syringe by the rearward action of the plunger in the syringe body and if necessary, assistance in this fluid transfer may be given by partial deformation of the outside walls of the container.

The invention is further described below with reference to preferred embodiments of the invention shown in the accompanying drawings wherein:

Figure 1 illustrates a front view of a unit dose container made in accordance with the invention sealed by a non resealable cap;

Figure 2 illustrates the top part of the unit dose container of figure 1 with the cap removed from the outlet opening;

Figure 3 illustrates the top portion of an alternative embodiment of the invention.

Figure 4 illustrates the unit dose container of figure 2 with a syringe connected to the outlet opening thereof; and

Figure 5 is an exploded view of the connection between the outlet opening and the syringe fitting as illustrated in figure 4.

In figure 1 there is shown a container 1 of thermoplastic material which can be readily deformed. Suitable materials for the manufacture of such containers are

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well known in the art but include polyethylene and polypropylene. The container 1 comprises a body portion 2 and a neck portion 3. At the end of the neck portion, there is provided a non resealable cap 4 connected to the end of neck 3 along weakened line 5. Neck portion 3 is in the form of an outwardly widening truncated cone and this feature is easier to identify in figure 2.

In figure 3 there is shown an alternative embodiment of the invention wherein the top of the body is formed hexagonally and the body is strengthened by one yoke on each side.

The non resealable cap 4 may be removed from neck portion 3 by a rocking or twisting action and separates from the neck portion 3 along weakened line 5. After removal of the non resealable cap, there is revealed an outlet opening 7 at the end of neck portion 3 through which, liquid contained in container 1 may pass.

Neck portion 3 comprises a thread engagement portion being the shoulder 8 located about the peripheral edge of outlet 7. The neck portion also comprises a non engagement portion 9 of reduced cross sectional diameter. Figures 4 and 5 show the connection of such a container to a syringe so to facilitate transfer of the liquid contained in the container to the syringe. These figures illustrate a syringe having a luer lock needle fitting 10. This fitting has a central male cone 11, an outer peripheral wall 12 and a bottom wall 13. These walls form the boundary of an annular channel 14. A screw thread 15 is provided on the inside wall of peripheral wall 12. The central luer cone 11 is provided with a

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transfer channel 16 which is open at its outer most end 17.

In figure 3, the engagement portion has a less sharply defined edge. This shoulder is adapted to engage with the screw thread fitting of the syringe but may require continued application of force during connection with the screw thread to ensure engagement. The neck is strengthened by yokes 6 and the top of the package is hexagonally formed.

The container 1 is adapted to engage with the luer lock fitting 10 as follows. After the non resealable cap 4 is removed from container 1, it is held in an upright position and the syringe fitting 10 is located adjacent to the outlet opening 7 of container 1 whereby central luer cone 11 is inserted into the outlet opening 7. By relative rotation of the container with respect to the syringe fitting, thread engagement shoulder 8 on neck 3 is caused to engage with thread 15. To assist in initial engagement, the syringe fitting may be pushed slightly down into the outlet opening 7. Once the thread "takes", shoulder 8 fits behind the thread 15 and abuts against the underside 17 of the thread and the inside of peripheral wall 12. The non engagement portion 9 of neck 3 is of narrower cross section so that it does not interfere with the thread 15 but can move freely into channel 14 whilst the container is screwed onto the syringe fitting.

The internal diameter of neck 3 at point 19 is slightly smaller than the outside cross sectional diamter of cone 11. As can be seen in figure 5, this ensures sealing engagement between the components at the area generally designated by the numeral 20. The extent of the sealing at 20 improves as

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the container is screwed onto the luer lock fitting as in a standard luer cone, the side wall of the cone is slightly inclined with the base of the cone being of slightly increased diameter than the top of the cone.

Accordingly, as container 1 is screwed onto the screw thread fitting 10, that portion of the neck indicated at position 19 is forced outwardly to increase the internal diameter of the neck at this position. This causes stresses in the neck resulting in closer and tighter abuttment of portion 19 against the outside wall of cone 11 as the container is screwed onto the needle fitting.

In figure 5, there is also shown in hatch lines the position of the container once fully screwed onto the needle fitting. In this position, the top of the outlet opening 7 abuts against the base 13 of the needle fitting to further ensure sealing engagement of the container onto the needle fitting.

Once the container has been fully secured onto the needle fitting, transfer of the injectable solution in the container is easily effected by the rearward action of the plunger in the syringe body. Most preferably, the container side walls are flexible enough so that the container can partially collapse in the drawing out of the injection solution. Transfer of the solution can be assisted by squeezing the outside walls 21 of the container.

The container of the present invention can be filled with a solution of any drug which is suitable for injection but is particularly advantageous for use with aqueous solutions of autoclavable local anaesthetics such as

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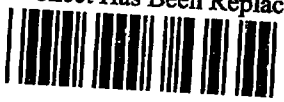
lidocaine, prilocaine, mepivocaine, bupivocaine, etidocaine or other drugs which are used under conditions where the demands for easy handling and sterility are especially high.

Finally, it is to be understood that various alterations, modifications and/or additions may be introduced into constructions and parts previously described without departing from the spirit or ambit of the invention as defined in the following claims.

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Claims:

1. A liquid containing thermoplastic unit dose container which comprises a body portion, a neck portion and an outlet opening at the end of the neck portion which is sealed by a non resealable cap, wherein the outside wall of the neck portion comprises a thread engagement portion which is located at or proximate the outermost edge of the neck portion so that after removal of the cap the thread engagement portion is adapted to engage within an inwardly facing screw thread channel at the end of a syringe, thus enabling sealing connection of the container to the said syringe so that liquid within the container may be directly transferred from the container to the syringe.

2. A container as claimed in claim 1 wherein the outside wall of the container neck comprises a thread engagement portion and a non engagement portion, said thread engagement portion being adapted to engage in the screw thread channel at the end of said syringe and said non engagement portion being shaped so that it does not interfere with the screw thread when the container is connected to the syringe.

3. A container as claimed in claim 2 wherein the thread engagement portion is located at the edge of the outlet opening and comprises a shoulder shaped to fit within the screw thread channel at the end of the syringe.

4. A container as claimed in any one of the previous claims wherein the neck portion is in the shape of an inverted truncated cone and the edge of the outlet opening is shaped to engage with the screw thread channel at the end of



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the syringe.

5. A container as claimed in any one of claims 1 to 3 wherein the neck portion has parallel sides.

6. A container according to any one of the previous claims wherein the top of the body is hexagonal and strengthened by one yoke on each side.

7. A container according to any one of the previous claims wherein the outlet opening is formed such that it is adapted to be screw threadingly engaged with a luer lock fitting.

8. A container as claimed in any one of the previous claims wherein the container is adapted to be connected to a syringe with a fitting comprising a central cone surrounded by a peripheral wall having an inwardly facing screw thread, characterized by the internal diameter of the neck portion of the container being less than or equal to the corresponding outside diameter of the central cone at at least one portion of the container neck.

9. A container as claimed in claim 8 wherein the engagement portion of the neck is greater in cross sectional diameter than the distance between opposite sides of the peripheral wall on the syringe to which it is intended to connect the container.

10. A container as claimed in any one of the previous claims wherein the non resealable cap is attached to the outlet opening along a weakened section.

11. A container substantially as hereinbefore described with reference to what is shown in any one of the accompanying drawings.

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UNIT DOSE CONTAINER

ABSTRACT

A liquid containing thermoplastic unit dose container (1) which comprises a body portion (2), a neck portion (3) and an outlet opening (7) at the end of neck portion (3) which is sealed by a non re-sealable cap (4). The outside wall of the neck portion (3) comprises a thread engagement portion (8) which is located at or proximate the outermost edge of the neck portion (3) so that after removal of cap (4) thread engagement portion (8) is adapted to engage within an inwardly facing screw thread channel (14) at the end of a syringe. This enables sealing connection of the container (1) to the syringe so that liquid within container (1) may be directly transferred from the container (1) to the syringe.

FIGURE 1

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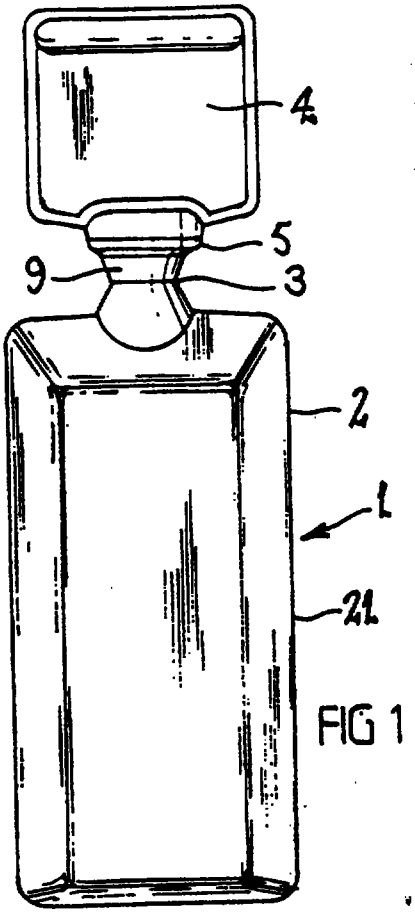


FIG 1

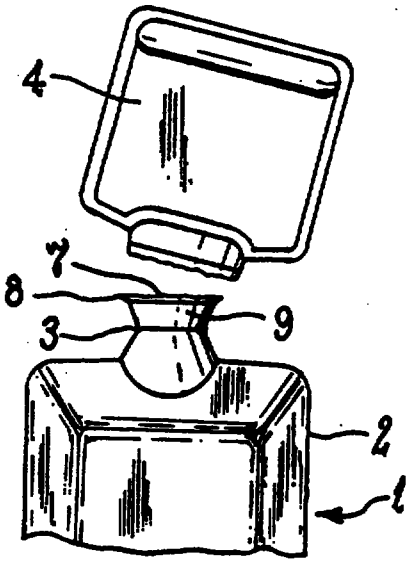


FIG 2

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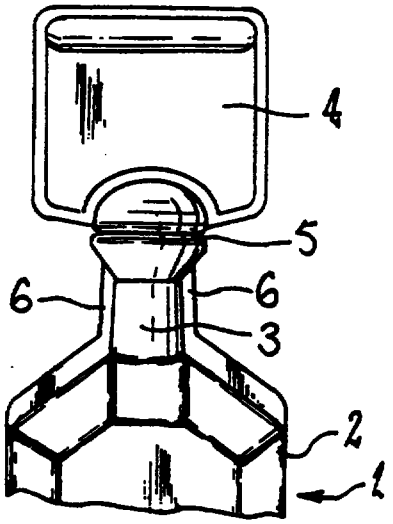


FIG 3

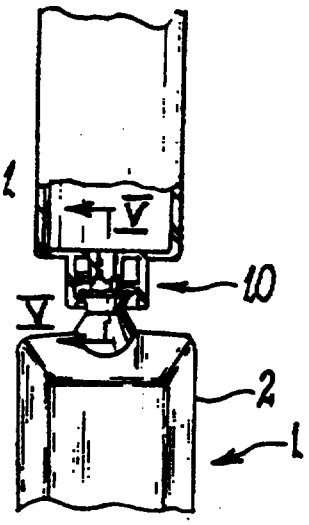


FIG 4

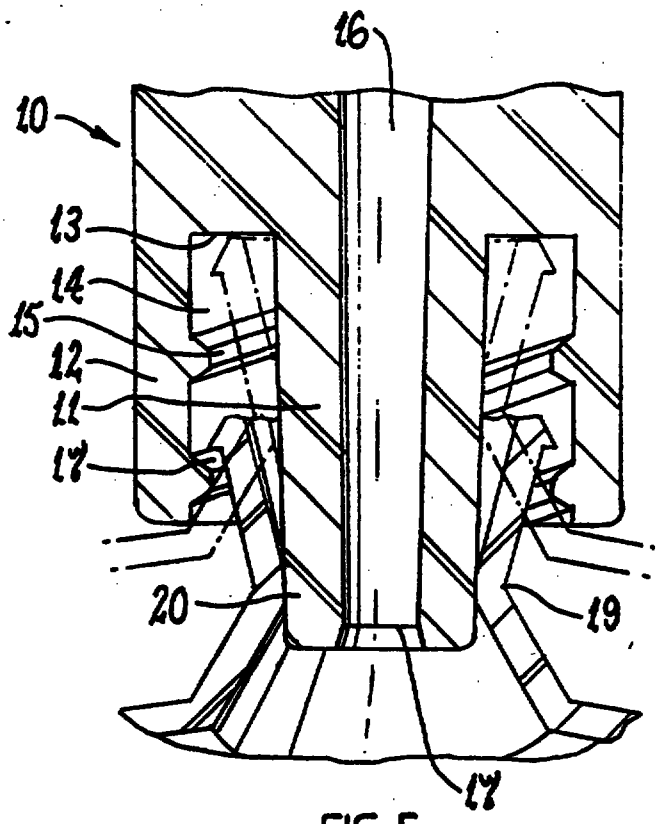


FIG 5

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UNIT DOSE CONTAINER

Description

This invention relates to a thermoplastic container suitable for use in holding and transferring injectable solutions to a syringe.

There are many different forms of syringe which are presently available for use by the medical professions. The most appropriate syringe design for any one situation depends largely on the particular circumstances of use, the nature of the solution being injected and the location of the intended injection.

One particular design difference between various syringes is the manner in which the open end is shaped to accommodate a hypodermic needle. The two most popular forms of needle fitting are the friction fit fitting (such as the luer slip fitting) and the combination of screw thread and friction engagement fitting (such as the luer lock fitting). Screw thread engagement fittings of interest in the context of the present invention are female fittings having an internal thread such as in the case of the luer lock fitting and all references to screw thread engagement fittings on syringes hereafter are references to female fittings. A screw thread engagement fitting is the fitting of preference where the circumstances of use indicate that there is some prospect of the needle becoming disengaged with the syringe body (e.g. epidural injections). This invention is particularly concerned with containers suitable for transferring injectable solutions to syringes having a screw thread engagement fitting.

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Background Art

In the past, the general practice of surgeons or other medical practioners using hypodermic syringes has been to transfer an injection solution to a syringe from a glass vial using a broad channelled needle attached to the syringe body. Following transfer, this broad channelled needle has been removed from the syringe and replaced with a narrower channelled hypodermic needle suitable for injecting the solution into the patient. It will be appreciated that this past practice has necessitated the use of a number of separate components. Furthermore, as solution transfer for injecting into humans requires scrupulous sterilizing of components, this previous practice has required separate sterilizing measures to be taken at each step.

To avoid the problems of such transfer, it has been previously proposed to provide ampoules or vials holding a single dose. These single dose vials have been adapted to fit like cartridges into a syringe body onto which can be fitted a hypodermic needle. Such unit dose vials are normally manufactured from glass and sealed with a rubber membrane and the vial is punctured by attaching to the syringe body a double sided needle.

An alternative arrangement is disclosed in Australian patent 556.483 where a unit dose container is described made from a thermoplastic material which is adapted to be opened and co-operatively engaged directly onto a needle fitting on a syringe to which it is desired to transfer injection fluid. Whilst this patent describes a satisfactory arrangement for use with a standard friction fit needle fitting such as a luer slip fitting, it does not deal with the problems associated with syringes utilising screw thread engagement systems such as the luer lock system.

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A similar container is known from EP-A-0 326 391. In this document a liquid containing thermoplastic unit dose container is described which comprises the features of the preamble of claim 1. The container thereby comprises a body portion, a neck portion, an outlet opening provided at the end of the neck portion and sealed by a non resealable cap, the neck portion is in the shape of an outwardly widening truncated cone having an engagement portion being provided at the edge of said outwardly truncated cone, said engagement portion being adapted to engage with the end of a syringe, thus enabling sealing connection of the container to the said syringe, so that liquid within the container may be directly transferred from the container to the syringe. However the container according to this document has several disadvantages. The engagement portion of the container described in this document is not constructed to be deformable and is not formed as a thread engagement portion intended to be inserted in a thread engagement fitting of a syringe and will therefore not provide an air tight sealing between the container and the syringe. The position and construction of the yokes prevents the insertion of the neck portion into the thread engagement fitting of a syringe. Moreover, as the cross section of the container is circular the walls of the body must be made thick in order to give the container the required stability when the cap is to be removed. This will make the withdrawal of the contents of the container into the syringe difficult.

The present invention provides a container suitable for use with a syringe having a screw thread engagement fitting to facilitate more secure, easier and more convenient transfer of an injection solution to a syringe which has a screw thread engagement fitting than has hitherto been possible.

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Description of the Invention

According to the present invention, there is provided a liquid containing thermoplastic unit dose container which comprises a body portion, a neck portion, an outlet opening provided at the end of the neck portion and sealed by a non resealable cap, the neck portion being in the shape of an outwardly widening truncated cone having an engagement portion being provided at the edge of said outwardly truncated cone, said engagement portion being adapted to engage with the end of a syringe, thus enabling sealing connection of the container to the said syringe, so that liquid within the container may be directly transferred from the container to the syringe. Said engagement portion is formed as a thread engagement portion being adapted to be inserted in an inwardly facing screw thread channel at the end of a syringe whereby said portion is slightly deformed thereby providing a sealing connection between the thread engagement portion of the container and the peripheral wall of the syringe. Furthermore, the top of said body portion has a hexagonal cross section.

The hexagonal form of the body of the container makes it easier to connect the container to the syringe as it strengthens the container in such a way that it can stand radial and axial strains better. Two yokes are preferably provided on either side of the ampoule substantially 180° to each other in order to further strengthen the body of the container. The yokes also reduce the risk of the container being punctured during production.

The container of the present invention is intended to be used with syringes having screw thread engagement fittings such as the "Luer Lock" fitting. The luer lock fitting comprises a central male cone, an outer

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peripheral wall and a bottom wall. The outside wall of the cone, the bottom wall and the inside of the peripheral wall together define an annular chamber. On the inside of the peripheral wall there is provided a screw thread. The thread engagement portion provided on the container preferably comprises a shoulder shaped to fit within the inwardly facing screw thread channel at the end of a Luer Lock syringe and said thread engagement portion is preferably formed such that it is adapted to be screw threadingly engaged within the Luer Lock fitting of a syringe.

Furthermore, the outlet opening of the container is formed to be adapted to a cone provided within the screw thread channel of the Luer Lock syringe to which the container is to be connected to.

The non resealable cap is attached to the outlet opening along a weakened section of the container so that it can be readily detached by a rocking or twisting action.

In order to facilitate the emptying of the container into the syringe the walls of the body of the container is made flexible in order to collapse when the contents is drawn into the syringe.

As the container of the invention is of a thermoplastic material, it is capable of slight deformation and the diameter of the neck portion in at least one position is most preferably slightly smaller than the outside diameter of the syringe so to sealingly abut against the cone at that point or points.

Where sealing engagement is facilitated in this manner, it is not necessary that the engagement portion of the container neck also provide a seal with the fitting although this is desirable. It is however very important that sealing engagement occur either between the engagement portion of the neck and the peripheral wall of the fitting or alternatively between a portion of the

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inside of the container neck and the central male cone. If there is no sealing connection, it is possible for the intrusion of unsterile air into the container and this may lead to contamination of the container contents of the syringe.

Sealing between the container and the syringe fitting is also enhanced if the engagement portion of the neck is slightly greater in cross sectional diameter than the internal diameter of the annular channel.

In use, the transfer of injection solution held within a container made in accordance with the invention is effected in the following way.

First, the non resealable container cap is removed by a rocking or twisting action and separates from the container along the weakened portion adjacent the outlet opening. The container is held in an upright position and the syringe into which it is intended to transfer the solution is placed so that the screw thread engagement fitting aligns with the outlet opening. The plunger in the syringe should be fully inserted. The container is then sealingly engaged with the syringe fitting by rotating the syringe and container with respect to each other until the container has completely engaged with the screw thread on the syringe. When so connected, the contents of the container may be conveniently withdrawn into the syringe by the rearward action of the plunger in the syringe body and if necessary, assistance in this fluid transfer may be given by partial deformation of the outside walls of the container.

The invention is further described below with reference to preferred embodiments of the invention shown in the accompanying drawings wherein:

Figure 1 illustrates a front view of a unit dose container made in accordance with the invention sealed by a non resealable cap;

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Figure 2 illustrates the top part of the unit dose container of figure 1 with the cap removed from the outlet opening;
Figure 3 illustrates the top portion of an alternative embodiment of the invention.
Figure 4 illustrates the unit dose container of figure 2 with a syringe connected to the outlet opening thereof; and
Figure 5 is an exploded view of the connection between the outlet opening and the syringe fitting as illustrated in figure 4.

In figure 1 there is shown a container 1 of thermoplastic material which can be readily deformed. Suitable materials for the manufacture of such containers are well known in the art but include polyethylene and polypropylene. The container 1 comprises a body portion 2 and a neck portion 3. At the end of the neck portion, there is provided a non resealable cap 4 connected to the end of neck 3 along weakened line 5. Neck portion 3 is in the form of an outwardly widening truncated cone and this feature is easier to identify in figure 2.

In figure 3 there is shown that the top of the body is formed hexagonally and the body is strengthened by one yoke on each side.

The non resealable cap 4 may be removed from neck portion 3 by a rocking or twisting action and separates from the neck portion 3 along weakened line 5. After removal of the non resealable cap, there is revealed an outlet opening 7 at the end of neck portion 3 through which, liquid contained in container 1 may pass.

Neck portion 3 comprises a thread engagement portion being the shoulder 8 located about the peripheral edge of outlet 7. The neck portion also comprises a non engagement portion 9 of reduced cross sectional

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diameter. Figures 4 and 5 show the connection of such a container to a syringe so to facilitate transfer of the liquid contained in the container to the syringe. These figures illustrate a syringe having a luer lock needle fitting 10. This fitting has a central male cone 11, an outer peripheral wall 12 and a bottom wall 13. These walls form the boundary of an annular channel 14. A screw thread 15 is provided on the inside wall of peripheral wall 12. The central luer cone 11 is provided with a transfer channel 16 which is open at its outer most end 17.

In figure 3, the engagement portion has a less sharply defined edge. This shoulder is adapted to engage with the screw thread fitting of the syringe but may require continued application of force during connection with the screw thread to ensure engagement. The neck is strengthened by yokes 6 and the top of the package is hexagonally formed.

The container 1 is adapted to engage with the luer lock fitting 10 as follows. After the non resealable cap 4 is removed from container 1, it is held in an upright position and the syringe fitting 10 is located adjacent to the outlet opening 7 of container 1 whereby central luer cone 11 is inserted into the outlet opening 7. By relative rotation of the container with respect to the syringe fitting, thread engagement shoulder 8 on neck 3 is caused to engage with thread 15. To assist in initial engagement, the syringe fitting may be pushed slightly down into the outlet opening 7. Once the thread "takes", shoulder 8 fits behind the thread 15 and abuts against the underside 17 of the thread and the inside of peripheral wall 12. The non engagement portion 9 of neck 3 is of narrower cross section so that it does not interfere with the thread 15 but can move freely into channel 14 whilst the container is screwed onto the syringe fitting.

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The internal diameter of neck 3 at point 19 is slightly smaller than the outside cross sectional diamter of cone 11. As can be seen in figure 5, this ensures sealing engagement between the components at the area generally designated by the numeral 20. The extent of the sealing at 20 improves as the container is screwed onto the luer lock fitting as in a standard luer cone, the side wall of the cone is slightly inclined with the base of the cone being of slightly increased diameter than the top of the cone.

Accordingly, as container 1 is screwed onto the screw thread fitting 10, that portion of the neck indicated at position 19 is forced outwardly to increase the internal diameter of the neck at this position. This causes stresses in the neck resulting in closer and tighter abuttment of portion 19 against the outside wall of cone 11 as the container is screwed onto the needle fitting.

In figure 5, there is also shown in hatch lines the position of the container once fully screwed onto the needle fitting. In this position, the top of the outlet opening 7 abuts against the base 13 of the needle fitting to further ensure sealing engagement of the container onto the needle fitting.

Once the container has been fully secured onto the needle fitting, transfer of the injectable solution in the container is easily effected by the rearward action of the plunger in the syringe body. Most preferably, the container side walls are flexible enough so that the container can partially collapse in the drawing out of the injection solution. Transfer of the solution can be assisted by squeezing the outside walls 21 of the container.

The container of the present invention can be filled with a solution of any drug which is suitable for injection but is particularly advantageous for use with aqueous solutions of autoclavable local anaesthetics such as lidocaine, prilocaine, mepivocaine, bupivocaine, etido-

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caine or other drugs which are used under conditions where the demands for easy handling and sterility are especially high.

Claims

1. A liquid containing thermoplastic unit dose container which comprises a body portion (2), a neck portion (3), an outlet opening (7) provided at the end of the neck portion and sealed by a non resealable cap (4), the neck portion being in the shape of an outwardly widening truncated cone having an engagement portion (8) being provided at the edge of said outwardly truncated cone, said engagement portion (8) being adapted to engage with the end of a syringe, thus enabling sealing connection of the container to the said syringe, so that liquid within the container may be directly transferred from the container to the syringe,
characterised in that said engagement portion (8) is formed as a thread engagement portion being adapted to be inserted in an inwardly facing screw thread channel at the end of a syringe, whereby said portion is slightly deformed thereby providing a sealing connection between the thread engagement portion (8) of the container and the peripheral wall of the syringe, and in that the top of said body portion (2) has a hexagonal cross section.

2. A container according to claim 1,
characterised in that two yokes (6) are provided substantially 180° to each other on either side of the body of the container.

3. A container according to claim 1 or 2,
characterised in that the thread engagement por-

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tion (8) comprises a shoulder shaped to fit within the inwardly facing screw thread channel at the end of a Luer Lock syringe.

4. A container according to claim 3, **characterised** in that the thread engagement portion (8) is formed such that it is adapted to be screw threadingly engaged within a Luer Lock fitting of a syringe.

5. A container according to claim 4, **characterised** in that the outlet opening (7) is formed to be adapted to a cone provided within the screw thread channel of the Luer Lock syringe.

6. A container according to any of the preceding claims, **characterised** in that the non resealable cap (4) is attached to the outlet opening along a weakened section of the container.

7. A container according to any of the preceding claims, **characterised** in that the walls of the body portion (2) of the container are flexible.

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UNIT DOSE CONTAINER

ABSTRACT

A liquid containing thermoplastic unit dose container (1) which comprises a body portion (2), a neck portion (3) and an outlet opening (7) at the end of neck portion (3) which is sealed by a non re-sealable cap (4). The outside wall of the neck portion (3) comprises a thread engagement portion (8) which is located at or proximate the outermost edge of the neck portion (3) so that after removal of cap (4) thread engagement portion (8) is adapted to engage within an inwardly facing screw thread channel (14) at the end of a syringe. This enables sealing connection of the container (1) to the syringe so that liquid within container (1) may be directly transferred from the container (1) to the syringe.

FIGURE 1

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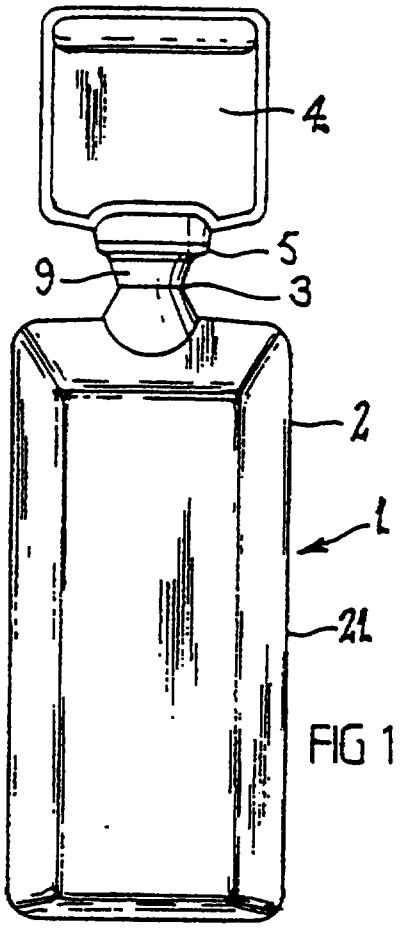


FIG 1

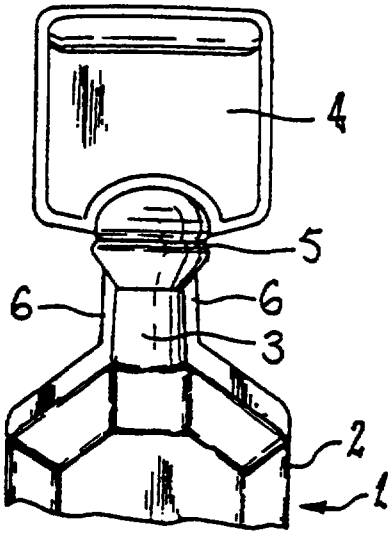


FIG 3

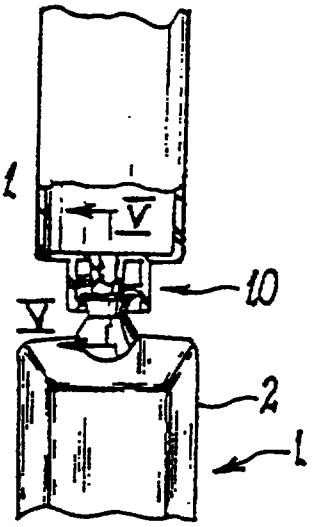


FIG 4

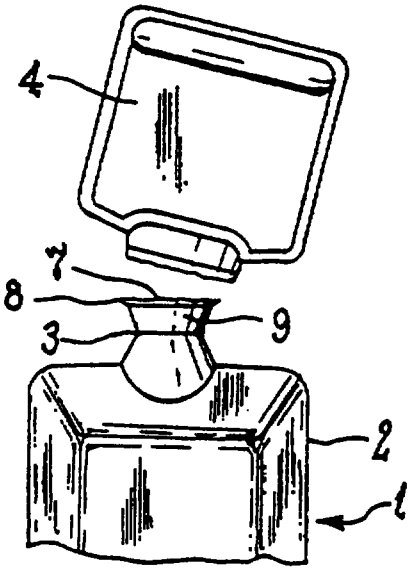


FIG 2

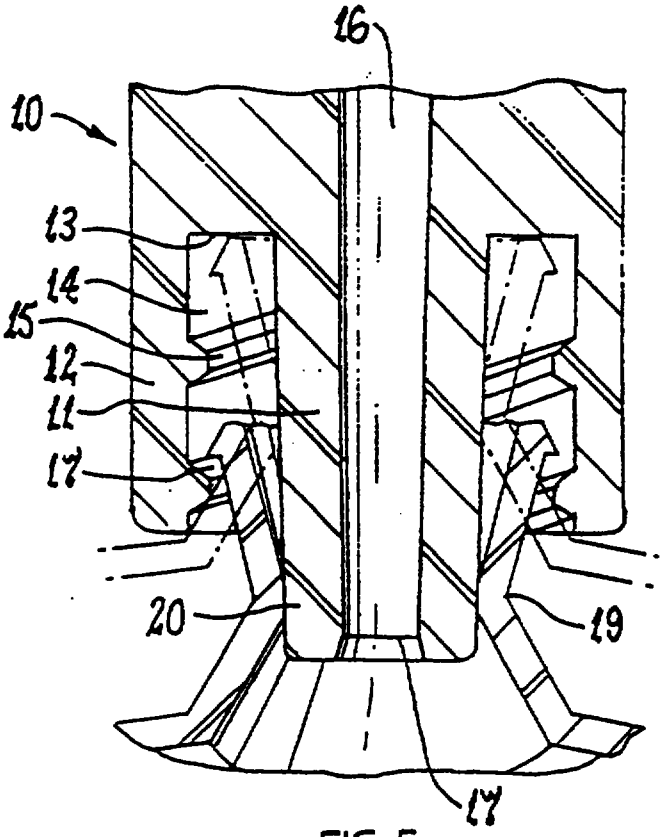


FIG 5

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caine or other drugs which are used under conditions where the demands for easy handling and sterility are especially high.

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Claims

1. A liquid containing thermoplastic unit dose container which comprises a body portion (2), a neck portion (3), an outlet opening (7) provided at the end of the neck portion and sealed by a non resealable cap (4), the neck portion being in the shape of an outwardly widening truncated cone having an engagement portion (8) being provided at the edge of said outwardly truncated cone, said engagement portion (8) being adapted to engage with the end of a syringe, thus enabling sealing connection of the container to the said syringe, so that liquid within the container may be directly transferred from the container to the syringe,
characterised in that said engagement portion (8) is formed as a thread engagement portion being adapted to be inserted in an inwardly facing screw thread channel at the end of a syringe, whereby said portion is slightly deformed thereby providing a sealing connection between the thread engagement portion (8) of the container and the peripheral wall of the syringe, and in that the top of said body portion (2) has a hexagonal cross section.

2. A container according to claim 1,
characterised in that two yokes (6) are provided substantially 180° to each other on either side of the body of the container.

3. A container according to claim 1 or 2,
characterised in that the thread engagement portion (8) comprises a shoulder shaped to fit within the inwardly facing screw thread channel at the end of a Luer Lock syringe.

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4. A container according to claim 3, characterised in that the thread engagement portion (8) is formed such that it is adapted to be screw threadingly engaged within a Luer Lock fitting of a syringe.

5. A container according to claim 4, characterised in that the outlet opening (7) is formed to be adapted to a cone provided within the screw thread channel of the Luer Lock syringe.

6. A container according to any of the preceding claims, characterised in that the non resealable cap (4) is attached to the outlet opening along a weakened section of the container.

7. A container according to any of the preceding claims, characterised in that the walls of the body portion (2) of the container are flexible.

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UNIT DOSE CONTAINER

ABSTRACT

A liquid containing thermoplastic unit dose container (1) which comprises a body portion (2), a neck portion (3) and an outlet opening (7) at the end of neck portion (3) which is sealed by a non re-sealable cap (4). The outside wall of the neck portion (3) comprises a thread engagement portion (8) which is located at or proximate the outermost edge of the neck portion (3) so that after removal of cap (4) thread engagement portion (8) is adapted to engage within an inwardly facing screw thread channel (14) at the end of a syringe. This enables sealing connection of the container (1) to the syringe so that liquid within container (1) may be directly transferred from the container (1) to the syringe.

FIGURE 1